REMARKS

Status of the Claims

Claims 1 and 31 have been reworded as product claims instead of product-by-process claims. In these claims, the recitation "wherein the water-soluble pharmacologically active ingredient and the adsorbent are contained in fine granules" is based on "fine granules prepared by granulating a mixture of a water-soluble pharmacologically active ingredient and an adsorbent."

Regarding claim 17, the step of "mixing fine granules prepared by granulating" has been reworded as two steps: of "granulating" and "mixing prepared fine granules."

In claim 61, "a water-soluble pharmacologically active ingredient, an adsorbent, D-mannitol and a disintegrator" is amended to "fine granules comprising a water-soluble pharmacologically active ingredient, an adsorbent, D-mannitol and a disintegrator" based on original claim 47. The text "wherein the water-soluble pharmacologically active ingredient, the adsorbent, the D-mannitol and the disintegrator are contained in fine granules" and "wherein the tablet is a compression molding tablet" are based on original claims 47, also.

In claims 12-14, 28-30, 42-44, 58-60 and 72-74, "compounding ratio" has been replaced with "amount."

In claims 4, 20, 34, 50 and 64, "the average particle size of the primary particles is in the range of 10 to 300 μm" is based on paragraph 116 of the published application, which states:

> As D-mannitol contained in the intraorally rapidly disintegrable tablets of the present invention, commercially available one may usually be used, which may be further processed by spray drying. It is preferable that the whole or a part of D-mannitol exists in a state of primary particles, which may preferably be prepared in a form of primary particles having the desired average particle

size and specific surface area by a pluverizer or a sieving machine. The average particle size of the primary particles is preferably in the range of 10 to 300 μm, more preferably, 30 to 100 μm. The specific surface area of the primary particles of D-mannitol is preferably in the range of 1.0 m^2/g or less, more preferably 1.0 to 2.1 x 10^{-6} m^2/g, even more preferably 0.4 to 0.02 m^2/g."

No new matter has been added by these amendments.

Rejections Under 35 U.S.C. § 112

In view of the recitation of "amount" insteadt of "ratio", it is believed that the rejection of claims 12-14, 28-30, 40-44, 58-60 and 72-74 under 35 U.S.C. § 112 has been overcome.

Rejections Under 35 U.S.C. § 102

Claims 1-7, 9-10, 15, 17-23, 25-26, 31-37, 39-40, 45, 47-53, 55-56, 61-67, 69-70 and 75 stand rejected as anticipated by U.S. Published Application No. 2001/0001106 (hereafter "Yoshinari"). Claims 1-3, 7-11, 13-19, 23-27, 29-33, 37-41, 43-49, 53-57, 59-63, 67-71 and 73-76 stand rejected as anticipated by U.S. Published Application No. 2001/0014340 (hereafter ("Ohta"). Applicants respectfully request reconsideration of this rejection in view of the amendments above.

The Examiner states that since "composition that may be in the form of a tablet comprising D-mannitol and other various ingredients," "D-mannitol having a specific surface area of not less than about 1 m^2/g," "hardness of 20N or higher" and "pravastatin sodium having a solubility of about 100 mg/mL in water" are described in Yoshinari et al., claims 1-7, 9-10, 15, 17-23, 25-26, 31-37, 39-40, 45, 47-53, 55-56, 61-67, 69-70 and 75 thus are not novel.

Amended claim 1 recites "[a]n intraorally rapidly disintegrable tablet which comprises fine granules comprising a water-soluble pharmacologically active ingredient and an adsorbent selected from the group consisting of calcium silicate, light anhydrous silicic acid, synthetic

aluminum silicate, silicon dioxide and magnesium metasilicate aluminate, D-mannitol and a disintegrator, wherein the water-soluble pharmacologically active ingredient and the adsorbent are contained in the fine granules."

Amended claim 1 states that (i) "the water-soluble pharmacologically active ingredient and the adsorbent are contained in the fine granules contained tablet" and (ii) "an adsorbent selected from the group consisting of calcium silicate, light anhydrous silicic acid, synthetic aluminum silicate, silicon dioxide and magnesium metasilicate aluminate."

With respect to claims 17, 31, 47 and 61 as independent claims, those claims call for (i) "[a] water-soluble pharmacologically active ingredient and the adsorbent ... contained in the fine granules" (ii) "an adsorbent selected from the group consisting of calcium silicate, light anhydrous silicic acid, synthetic aluminum silicate, silicon dioxide and magnesium metasilicate aluminate."

Yoshinari et al. disclose "[a]n intraorally rapidly disintegrable tablet comprising a pharmacologically active ingredient and an adsorbent," but does not disclose "fine granules comprising a water-soluble pharmacologically active ingredient and an adsorbent selected from the group consisting of calcium silicate, light anhydrous silicic acid, synthetic aluminum silicate, silicon dioxide and magnesium metasilicate aluminate." Yoshinari et al. further discloses "granulating a mixture of a pharmacologically active ingredient and some other ingredients" (Example 3), but does not disclose "granulating a mixture of a pharmacologically active ingredient and an adsorbent selected from the group consisting of calcium silicate, light anhydrous silicic acid, synthetic aluminum silicate, silicon dioxide and magnesium metasilicate aluminate."

In view of the foregoing, it is respectfully submitted that this ground of rejection has been overcome.

The Examiner points out that since "a rapidly disintegrating tablet comprising various ingredients," that "magnesium stearate is coated on a metal mold and dies of a hydraulic press," disintegration time of less than 30 seconds and hardness properties comparable to the claimed 20N

or higher," "the claimed ratio of pharmacologically active ingredient to adsorbent as being from 1:10 to 10:1, weight percentages of D-mannitol being about 60-95% and the disintegrate being about 1-10%" and "method of making the invention including the steps of granulation and compression" are described in Ohta, et al. Accordingly, according to the Examiner, claims 1-3, 7-11, 13-19, 23-27, 29-33, 37-41, 43-49, 53-57, 59-63, 67-71 and 73-76 are not novel.

Amended claims 1, 17, 31, 47 and 61 as independent claims call for (i) "[a] water-soluble pharmacologically active ingredient and [an] adsorbent ... contained in ... fine granules" and (ii) "an adsorbent selected from the group consisting of calcium silicate, light anhydrous silicic acid, synthetic aluminum silicate, silicon dioxide and magnesium metasilicate aluminate."

Ohta et al. discloses "[a]n intraorally rapidly disintegrable tablet comprising a pharmacologically active ingredient and light anhydrous silicic acid," but does not disclose "[i]n fine granules comprising a water-soluble pharmacologically active ingredient and an adsorbent selected from the group consisting of calcium silicate, light anhydrous silicic acid, synthetic aluminum silicate, silicon dioxide and magnesium metasilicate aluminate." Ohta et al. further discloses "granulating a mixture of a pharmacologically active ingredient and some other ingredients, then mixing resulted granulations and lubricant (such as light anhydrous silicic acid)," but does not disclose "granulating a mixture of a pharmacologically active ingredient and an adsorbent selected from the group consisting of calcium silicate, light anhydrous silicic acid, synthetic aluminum silicate, silicon dioxide and magnesium metasilicate aluminate."

It is respectfully submitted that the rejection over Ohta has been overcome.

CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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